



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

DEC 6 2002

Food and Drug Administration  
College Park, MD 20740

Mr. D. J. Soetaert  
President  
International Tree Nut Council  
Nutrition Research and Education Foundation  
2413 Anza Avenue  
Davis, CA 95616

RE: Health Claim Petition – Nuts and Coronary Heart Disease.

Dear Mr. Soetaert:

This letter is in reference to the health claim petition that you submitted on August 28, 2002, on behalf of The International Tree Nut Council Nutrition Research and Education Foundation. We informed you on September 13, 2002, that the date by which FDA would either file or deny your petition is December 6, 2002. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)). Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act requires FDA to either issue a proposed regulation to take the action requested in the petition, or to deny your petition, not later than 90 days after the date of filing the petition. If FDA does not act within these 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. This 90 day period will expire on March 6, 2003.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

Kathleen C. Ellwood, Ph.D.  
Acting Director  
Division of Nutrition Science and Policy  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

cc: Guy H. Johnson, Ph.D.  
Stephen H. McNamara, Esq.

02P-0505

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